

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 361/03	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/DE2004/000758	International filing date (day/month/year) 08.04.2004	Priority date (day/month/year) 10.04.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant KRETSCHMANN, Harald		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>10</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DE2004/000758

Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-8 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 22-24 _____ received by this Authority on 30.03.2005 by fax
- nos.* 1-21 _____ received by this Authority on 22.06.2005 with the letter of 17.06.2005
- ☒ the drawings:
- sheets 1/15-15/15 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DE2004/000758

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-21	YES
	Claims		NO
Inventive step (IS)	Claims	1-21	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

1. Observations regarding the clarity of claim 1 (PCT Article 6)

1.1 In claim 1 the housing is defined such that it consists of two housing parts that are matched one to the other, i.e. the housing should not contain any other parts. Should this be the case, it would be doubtful whether the embodiments in figures 3, 4 and 9 would still fall under the definition of claim 1. In any case, the embodiment in figure 6 appears not to fall under claim 1.

1.2 Claim 1 states on the one hand that the supply channel forms one or more bars and on the other hand that the bars together with the side part of the housing parts form the supply channel. These definitions appear to be somewhat redundant.

2. Reference is made to the following documents:

D1: WO-A-01/56618

D2: EP-A-0069037

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

2.1 D1 discloses a sterilisation device that consists of a housing with a plurality of housing parts, a test chamber (see figure 1) with an indicator and with apertures and supply lines for supplying the sterilisation medium.

The sterilisation device comprises a housing that consists of two housing parts that are matched one to the other.

In one housing part, a supply channel is formed in such a way that the arrangement thereof inside the housing part forms a plurality of bars, between which the supply channel lies. The bars and the housing parts are sealed in relation to the outside and to each other in a sterilisation medium-tight manner.

On the outer edge of the housing part, the bar and/or bars form(s) the supply channel, at least partly with the side part of the housing parts.

The device as per the current claim 1 differs from that of D1 in that the supply channel also forms the base of the test chamber, in which the indicator is placed.

This distinguishing feature makes it possible to avoid weak points in the join between the supply line and the test chamber (see page 1, lines 22 and 23 of the description).

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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2.2 D2 discloses a sterilisation device (see figure 6) that consists of a housing with a plurality of housing parts, a test chamber with an indicator and with apertures and supply lines for supplying the sterilisation medium. The sterilisation device comprises a housing that consists of two housing parts (1, 3) that are matched one to the other.

In one housing part (3), a supply channel (see "canaux" on page 7, line 13) is formed in such a way that the arrangement thereof inside the housing part forms a plurality of bars, between which supply channels lie.

The supply channels also form the base of the test chamber (see "alvéoles" 7, 8 on page 7, lines 12-15), in which the indicator is placed and the sterilisation medium passes from the outside directly via the aperture to the supply channels and the indicator.

The device as per the current claim 1 appears to differ from that of D2 essentially in that the bars and the housing parts seal the supply channels in relation to the outside and to each other in a sterilisation-medium tight manner.

This distinguishing feature permits long supply channels and would appear to be known per se.

However, this appears not to be of interest in the

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
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sterilisation testing device from D2. In D2, the housing parts are open at least along an entire length. The aim in D2 is to prevent the indicator from coming into contact with the parts to be sterilised. There is therefore no incentive to modify the device as per D2 in an obvious way and thereby arrive at the definition as per the current claim 1.

2.3 Novelty (PCT Article 33(2)) and inventive step (PCT Article 33(3)) must therefore be acknowledged in respect of the subject matter of claim 1.

Claims 2-21 are dependent on claim 1 and therefore likewise meet the PCT requirements for novelty and inventive step.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DE2004/000758

Box No. VI **Certain documents cited**

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
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2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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See Supplemental Box

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DE2004/000758

Box No. VII **Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

1. Claim 1 is drafted in the two-part form pursuant to PCT Rule 6.3(b). Proceeding from D1 or D2 as the closest prior art, the two-part form would appear to drafted incorrectly.

2. D1 should be acknowledged in the description (PCT Rule 5.1(a)(ii)).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/DE2004/000758

Box No. VIII **Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The additional features in dependent claim 4 would appear to indicate merely a desired result and are therefore not suitable for further defining the device as per the preceding claims (PCT Article 6). In addition, the phrase "under normal sterilisation conditions" is vague and unclear.

2. As already mentioned in Box V, item 1.1, claim 1 is worded such that the housing consists of only two parts. It is therefore unclear whether the seal 12 in claim 12 is intended as a further part of the housing.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box VI**Certain documents cited**

Documents DE-A-10213066 (D3) and EP-A-1308175 (D4) were published after the priority date of the current application, but have an earlier priority date. D4 could become relevant during the regional European phase.